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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,572	04/28/2006	Ushio Iwamoto	P28765	8899

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/559,572	IWAMOTO ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 0809*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-139* is/are pending in the application.

4a) Of the above claim(s) *91-104 and 121-136* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *105-120 and 137-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This Office Action is in response to the Applicant's reply received 9/8/09. Claims 91-139 are pending. Claims 91-104 and 121-136 are withdrawn. Claims 1-90 are cancelled. Claims 105, 108, 109, 112-115, 118 have been amended. No Claims are new. Claims 105-120 and 137-139 are considered in this Office Action.

Response to Applicant's Amendments

In the response submitted by the Applicant the following 35 U.S.C § 102 rejections are withdrawn:

- Claims 105 and 120 as being anticipated by Read et al. (U.S. Patent # 5651966, 1997) with support by Wakelyn et al. (Handbook of Fiber Chemistry, 1998)

The following 35 U.S.C § 103 (a) rejections are withdrawn:

- Claims 105-107, 115, and 120 as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) as applied to 105 and 120 above in light of support by Seagull et al. (J. Cotton Science).
- Claims 105-115, 118-120 and 137-139 as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) as applied to claims 105-107, 115, and 120 above, and further in view of Onodera et al. (U.S. Patent # 5407581, 1995) in light of support of Jan et al. (J. General Physiology, 1973)

The Applicant's amendments limiting that the steps "comprises extracorporeally contacting at least living leukocytes" as opposed to platelets *or* leukocytes as previously limited necessitated the above withdrawal.

However the Examiner notes that the method now requires that living leukocytes be included in the step but there are no limitations that platelets must therefore be excluded, only that they are not a minimum requirement of the claims. The open language of "contacting at least living leukocytes" does not eliminate art that includes materials with both leukocytes and platelets or indeed other materials as well.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 105-107, 115-117, and 120 over Read et al. (U.S. Patent # 5651966, 1997) and support in view of Britton et al. (U.S. Patent Publication # 2003/007957, January 2003) were considered but not found persuasive.

The Applicant argues that "Britton is only used in an attempt to try and establish use of fibroblasts or fibrins" and simply states "Applicants' claimed subject matter would not be at hand". However the Applicant does not provide any further argument why Britton et al. does not cure the deficiencies of Read et al. nor if their combination is improper.

Indeed Britton et al. teach their invention impregnates **platelet-rich plasma** (**PRP**) that comprises platelets (like Read et al.) as well as fibrin, plasmin, plasma proteins and white blood cells (leukocytes) into bandages for wound healing (paragraphs 8 and 33). While Read et al. only focuses on platelets from platelet-rich plasma for their bandages (Read Example 2), it is clear from Britton et al. that leukocytes as well as platelets are important in wound healing such as improving collagen deposition to enhance endothelial cell growth, that it would be obvious to one

of ordinary skill in that art to add both to such a bandage (Britton,paragraph 7). Furthermore since both are for methods of making bandages for wound healing, it would be obvious to combine both methods to create an improved wound healing bandage (MPEP 2144.06 I).

Britton et al. does not explicitly teach that their leukocytes are "living". However Britton et al. is clear that "white blood cells...within the platelet and fibrin matrix creates a healing milieu" (Britton, paragraph 7). It is known in that the art that the blood healing milieu of platelets and leukocytes requires the leukocytes to be live and vital as supported by Faraday et al. (pg 145 introduction) since the leukocytes must release various substances (pg 145, col 2, last paragraph) to enhance platelet functions. Furthermore Faraday et al. also teaches that the common methods of isolating leukocytes from whole blood such as centrifugation does not destroy them (Faraday, pg 146, paragraph bridging col. 1 and 2). Since Britton et al. only uses centrifugation of whole blood to isolate their PRP with leukocytes then inherently the leukocytes are living (Abstract and paragraph 35).

Therefore Read et al. and Britton et al. in light of support from Faraday et al. continue to read on the claimed invention. As such the rejection is rephrased below with adjustments to include the new support by Faraday et al.

Claims 105-107, 115-117, and 120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al. (U.S. Patent # 5651966, 1997) in further in view of Britton et al. (U.S. Patent Publication # 2003/007957, January 2003) with support by Wakelyn et al., Seagull et al. and Faraday et al.

These claims are to a method of preparing a wound-healing promoting material comprising the following steps:

- Extracorporeally contacting at least living leukocytes with a sheet-shaped porous body to trap them on the surface of the pores.

Read et al. teach that bandages can be made from woven or nonwoven cotton (col 4, lines 50-60). They teach these bandages are contacted with an aqueous solution of platelets which causes them to adhere to the cotton (col 4, lines30-35). Woven or nonwoven cotton inherently has pores as supported by Wakelyn et al. and also since cotton sheets are a collection of overlayed fibers that inherently form pores (see M.P.E.P. § 2112 IV for Examiner's Burden of Inherency).

Claims 106 and 107 define the dimensions of the fabric and limit it to a nonwoven fabric. Read et al. teach that their bandage is made of nonwoven cotton. However they do not explicitly teach the diameter of the cotton fibers. However as supported by Seagull et al. common cotton fibers used in textiles have a diameter between 14 and 28 micrometers (pg 100, Figure 2). Therefore it would be obvious that the cotton of Read et al. would have a diameter between 0.3 to 50 micrometers. What Read et al. does not teach is the thickness or the bulk density of the cotton bandage. However, one of ordinary skill in the art would recognize that the size and density of the cotton bandage are result effective variables. This would depend on the use, the type and size of the wound the bandage is expected to cover and the amount of bleeding expected. Indeed one of ordinary skill in the art would recognize that a common drug store or first aid kit has a multitude of bandages ranging from small circles for paper cuts to thick,

absorbent self-adhesive pads for more severe injuries. Absent any teaching of criticality by the applicant concerning these limitations, it would be *prima facie* obvious that one of ordinary skill in the art would recognize these limitations are result effective variables which can be met as a matter of routine optimization (M.P.E.P. § 2144.05 II).

Claim 115 limits that the sheet-shaped porous body with platelets is further cultured. Read et al. teach that bandages, mesh and dressings that are impregnated with platelets induce wound healing (Example 10). One of ordinary skill in the art would recognize that since wound healing occurred and was accelerated after the dressing was applied and the healing was accelerated by the dressing, then it obviously the dressing with platelets took part in the culturing of new cells to heal the wound.

While Read et al. teach a sheet shaped porous body with platelets trapped on the surface. They do not teach the addition of living leukocytes, fibroblasts or fibrins. Regardless this would be obvious in view of Britton et al. They desire to make a bandage impregnated with an autologous platelet-rich plasma as a pharmaceutical preparation to accelerate wound healing (Britton, Abstract and paragraph 33). They teach that their platelet rich plasma comprises platelets, white blood cells (leukocytes), plasma and plasma proteins (Britton, paragraph 8). It would be obvious to combine the teachings of Britton with the bandage of Read et al. since both are directed towards wound healing and both incorporate platelets into a bandage. Therefore this is simply using the teachings of Britton et al. to improve a similar bandage of Read et al. that already incorporates some of the materials such as platelets impregnated on a bandage, as Britton (KSR Int'l Co. v. Teleflex, Inc. 550 U.S. 398 (2007)).

While Britton et al. does not explicitly teach that their leukocytes are "living". However Britton et al. is clear that "white blood cells...within the platelet and fibrin matrix creates a healing milieu" (Britton, paragraph 7). It is known in that the art that the blood healing milieu of platelets and leukocytes requires the leukocytes to be live and vital as supported by Faraday et al. (pg 145 introduction) since the leukocytes must release various substances (pg 145, col 2, last paragraph) to enhance platelet functions. Furthermore Faraday et al. also teaches that the common methods of isolating leukocytes from whole blood such as centrifugation does not destroy them (Faraday, pg 146, paragraph bridging col. 1 and 2). Since Britton et al. only uses centrifugation of whole blood to isolate their PRP with leukocytes then inherently the leukocytes are living (Abstract and paragraph 35).

Therefore claims 105-107, 115-117, and 120 are obvious in view of the above references.

New Rejections Necessitated by Amendment

While the combination of Read et al., Britton et al. and Onodera et al. are new, all three references were presented earlier in other rejection combinations. The Applicant agues that Onodera et al. does not relate to Read et al. since Onodera et al. is for filtering blood components and not necessarily for making a bandage and it would not be obvious to combine the two teachings. However both Read et al. and Britton et al. are quite clear they want PRP that contains both platelets and leukocytes to adhere to their bandages. Both Read et al. and Britton et al. use similar materials such as cellulose (such as cotton) in their method to adhere the PRP to the bandages. Onodera

et al. clearly teach a method of modifying these materials to improve their adhesion of the PRP. Therefore it would be obvious for one of ordinary skill in the art to use the teachings of Onodera et al. to improve the material in their bandages since both Read et al. and Britton et al. desire to adhere PRP to these bandage materials. Therefore this new combination of Read et al., Britton et al., and Onodera continue to read on the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 105-120 and 137-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Read et al., Britton et al. and supporting references as applied to claims 105-107, 115-117, and 120 above, and further in view of Onodera et al. (U.S. Patent # 5407581, 1995) in light of support of Jan et al. (J. General Physiology, 1973).

While Read et al. and Britton et al. teach a wound healing material with living leukocytes and fibrin attached to the surface of the pores in a sheet, they do not teach that the platelets were obtained by the filtering steps limited in the claims or that the source is fresh blood filtered in through the sheet. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Onodera et al.

Onodera et al. teach that the surface of filter media such as cotton and porous sponges can be modified via methods such as graft copolymerization, radiation or plasma treatment, or covalent bonding of ligands on the surface (Onodera et al. col 16, lines 1-10). Onodera et al. teach that the purpose of these modifications is to obtain a filter media with a surface electric change of greater than -30 μeg/g (Onodera, col 5, lines 10-15). Onodera et al. teach that as the surface electric charge is increased then the adhesion of platelets is increased (Onodera et al. col 17, lines 45-47). Onodera et al. also teach that modifying the pores size of the sheets can also increase the affinity of platelets (Onodera et al. col 21, lines 5-12). Indeed Onodera et al. teach the pore size should be from 1 to 100 μm (col 14, lines 20-25). Onodera et al. teach that leukocytes are selectively bound to a sheet with this negative surface electric charge (Onodera, col 23, lines 30-35). This charge interaction would inherently exclude erythrocytes since their surface is negatively changed and thus repelled by a negative surface charge as supported by Jan et al. (Introduction, 1st paragraph).

Onodera et al. also teach that the porous sheet can placed inside an openable container with an inlet and outlet ports (Onodera, col 23, lines 33-44 and Example 26). Onondera et al. teach that extracorporeal blood products such as plasma, fresh whole blood, leukocyte-containing red cell product, leukocyte containing platelet product or leukocyte containing plasma product can be passed immediately through the filter via the inlet ports and outlet ports (Onodera, col 23, lines 33-44, col 27, lines 33-37 and Example 26). Onodera et al. teach that the filter is washed since the porous sheet is continuously flushed with the sample even after initial contact with the blood cell

suspension (Example 21, col 65, lines 30-45). Therefore one of ordinary skill in the art would recognize that the initial blood placed into the suspension would initially bind the platelets or leukocytes and the remaining blood would wash over those initially bound platelets.

In the example by Onodera et al. they do not specifically mention that the container is liquid tight. However one of ordinary skill in the art would read that the container of Onodera et al. did not spill or leak and that spilling blood products is a potential biohazard, therefore it would be obvious to one of ordinary skill in the art to make the container liquid tight. Also Onodera et al. does not teach the exact source of his blood, however they do teach that the treatments are for humans (Onodera, col 10, line 9, col 14, line 59, col 27, lines 19) it would be obvious to one of ordinary skill in the art to use human blood which has mature cells such as erythrocytes. Furthermore it would be obvious to one of ordinary skill in the art to use either autologous blood or blood from a matching donor since both are art-recognized equivalents for the same purpose (M.P.E.P. § 2144.06).

It would be obvious to one of ordinary skill in the art to combine the teachings of Onodera et al. with Read et al. and Britton et al. since both share common materials such as cotton to teach a method that at the very least trap platelets. Read et al. and Britton et al. desire to attach PRP with platelets and leukocytes to their cotton bandage. Onodera et al. teaches methods of modifying cotton and other materials to provide both pore size and surface charge to selectively adhere platelets and leukocytes. Therefore one of ordinary skill in the art would recognize that the known work in the field taught by

Onodera et al. would prompt a variation in the bandage of Read et al. and Britton et al. since they teach the same materials as well as a common goal to selectively adhere platelets and leukocytes to that common material ((KSR Int'l Co. v. Teleflex, Inc. 550 U.S. 398 (2007)).

Therefore claims 105-120 and 137-139 are obvious in view of the above references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for

interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Leon B Lankford/
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